REMARKS

With careful attention to the Action dated October 2, 2003, the application has been amended as requested above in order to place it in condition for allowance. Applicants gratefully acknowledge, for the record, the allowance of the method claims, claims 67, 68 and 69. The Applicants also note that the drawings presented with the Preliminary Amendment have been approved.

Claim Rejections under 35 U.S.C. § 112

The Examiner has rejected claims 38 - 66 under 35 U.S.C. 112, second paragraph, as being indefinite because the Examiner was unable to determine the metes and bounds of the claims (pages 3 and 4 of the Action), because sizes of all elements have not been specified. Firstly, Applicants traverse the Examiner's basis for rejection as being improper as the positions and relationships of the elements to one another are specified in the claims it appears that Examiner is suggesting that the Applicants unnecessarily narrow the claims based on the sizes of the various parts. Reasonable variations in size which are not surprising or unexpected in the art are not relevant to the determination of patentability. As is clear from the art of record and from general knowledge in the medical community, anyone skilled in the art of ostomy devices will necessarily understand the approximate sizes of a faceplate of an ostomy port and any pads or other parts associated therewith. Nonetheless, in order to assist the Examiner with understanding the size of the claimed devices for purposes of comparison with the references, the Applicants provide the following comments:

The Examiner states that the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it

is most nearly connected, to make and/or use the invention." Being such ones skilled in the art, Applicants respectfully disagree. It is submitted that there is ample disclosure in the specification, including the drawings to readily enable practice of the invention. Surgical creation of stomas in patients has been known very a long time and for those familiar with such stomas it is well known that the size varies with the patient and the particular procedure performed, as explained in the original specification. The continent ostomy port with which the presently claimed pad is used and sized to fit is explained as varying, as required for a given patient's body. For example a neonate will have a much smaller stoma than a 300 pound man, but the relative size is familiar to one skilled in the art. In the original application, page 10, lines 27 – 30, it is stated, "As will be clear to one skilled in the art, after review of the following description, the new device 10 can be initially sized for an individual user and placed or "implanted" very easily in a clinic or office by a trained medical professional." In this art, those "skilled" are highly educated, clinically trained individuals; i.e., "trained medical professionals" who will have no confusion as to what is an appropriate size port and faceplate thereof for use on a particular individual. Further, on page 12, line 27 – through page 13, line 3, "Catheter member 14 is preferably generally tube-shaped and usually extends substantially perpendicularly to the plane of plate 12. However, catheter 14 is shaped and sized in diameter and length appropriately for the particular type of stoma for which the new COP is intended, it being understood that the new port is suitable and readily adapted or various types of ostomies and to any size of ostomate, as discussed in the Background portion above. Ordinarily the outside diameter of catheter member 14 will not be so large that the port device cannot be gently manually turned or "twirled" within its seat in the stoma."

As Examiner has noted, an example of the size of the aperture in the pad is given. This is provided as an example of the type of variation that can occur. At the top of page 14, first paragraph it is explained that, "It is expected that various sizes of pad 58 will be provided, depending, among other things, upon the user's size. For example, pad 58 can be made with the aperture 60 increasing in ¼ inch increments, from approximately 1 inch to about 2 ¾ inches." Later on that page, it is stated that, " The shape of the perimeter of second proximal level 66 of pad 58 may be generally oval, round, or otherwise, as however is economical and convenient to manufacture and comfortable to use, and which is function as described with regard to the shape and of the particular form of port 10. Likewise, if plate 12 is not substantially flat, but instead takes some other form, such as being arched, domed, or whatever suits the particular clinical circumstances then pad 58 can be modified accordingly to fit beneath such modified plate shape." In this regard, Figs. 1 – 3 clearly show the shape of one type of the new COP which can accommodate the pad illustrated in claim 4 and featured in Claim 38 and the dependent claims thereof. The pad shown in figure 4 is obviously circular with an elliptical upper level having a flat upper surface, which, as described in the text, could be domed or of some other shape if necessitated by the shape of the COP faceplate. It is Applicants' position that the above provides amble and enabling disclosure to one skilled in the art to practice the invention, particularly because the COP and faceplate thereof are thoroughly described in the specification and drawing of the application as originally filed.

Similarly, the text and drawings of the Preliminary Amendment provide sufficient support for the structure of the pads featured in claims 43, 47 and 59 and their respective dependent claims. For example, in the Preliminary Amendment there have been added Figures 28 through 35 and the descriptions thereof. Figures 28 through 30 show the shim and its

dimensions. This shim is featured in the combination claims 59 – 66. As Fig. 34 shows the underside of a COP faceplate with the area into which shim 157 fits, the relative size of the faceplate, and therefore the pad can be estimated from the size of the shim.

Further description of the shim and new pad can be found in the portions of the specification added in the Preliminary Amendment, for example, "**Shim 157 is substantially flat and in the preferred embodiment shown has a generally oval-shaped perimeter 157a, as illustrated in Fig. 28. Perimeter 157a is shaped to match the perimeter of pad 158. Thus, if the shape of the pad is something other than oval, if desired, the exterior perimeter of shim 157 can be altered accordingly. The overall size of shim 157 can vary, as desired, to either match the size of moisture barrier/pad 158, so as to act as a riser for the COP face plate, or the shim may be sufficiently smaller in exterior dimension to permit it to be seated within the underside (proximally) of COP 200 for enhanced absorption of stomal fluids.**

The sectional views shown in Figs. 29 and 30 illustrate an example of useful dimensions (in inches) for shim 157, but it is foreseen that other dimensions will suffice, depending upon the particular circumstances of use, including stoma size and COP dimensions.

Shim 157 has a preferably circular interior side wall, which defines a through-hole 157b to surround the stoma. The size and shape of the throughhole can be varied as may be necessary to accommodate any variations in size and shape stomas of various individual users. The arrow indicated by "X" in Fig. 29 illustrates one useful surface site on shim 157 for optional application of an adhesive, such as a pressure sensitive adhesive and/or web adhesive, for example.

Figs. 31 - 35 illustrate an alternative embodiment, generally designated 158, of the new moisture barrier / pad. Inconsistencies in size between the figures may exist due to copying

anomalies. **In the preferred version shown, pad 158** is formed of molded foam material and has a low profile, as seen if Fig. 33, with **a generally oval perimeter 158a (Fig. 35), although other perimeter designs can be useful.** The **pad body 159 has an outer (distal) surface 159a that is slightly domed, but formed in the central portion thereof with an indented region that accommodates the distal portions of a COP, such as that generally designated as 200 in Fig. 32. In this embodiment, upper surface 159a is formed with a central depressed area that is generally cross-shaped, extends down into the body 159 and has a substantially flat floor 163. Floor 163 defines a central aperture 160 with a side wall 161, which is shown circular, but can be other shapes, if desired, to accommodate the shape of a catheter, such as that indicated at 214 in Fig. 32."**

Portions which specifically relate to the size and shape of the elements have been printed in bold to assist the Examiner. The portions of the specification added in the Preliminary Amendment continue with descriptions of the shape of the pad and it's interconnection with the COP and shim during use. For example, on page 5 of the Preliminary Amendment, "Channel 158c is optionally sized and shaped to correspond to and to receive shim 157, so that shim 157 is disposed in normal use between the bottom of pad 158 and the user's skin. Shim 157 can also be nested in the underside of pad 158 without the presence of ring 158b. This arrangement is especially useful if the shim is to provide wicking properties. Alternatively, as previously discussed, the shim can have exterior dimensions which correspond to the exterior perimeter dimensions of pad 158, or which even extend slightly beyond the perimeter of the pad." In view of the above points, the drawings and the specification of the application, it is Applicants' position that the claims are all well enabled by the specification.

IV. Conclusion

Accordingly, in addition to the claims already held to be allowable, claims 67 – 69, Applicants respectfully submit that independent claims 38, 43, 47 and 59, and all the claims which depend therefrom, are now in condition for allowance as particularly pointing out and distinctly claiming the subject matter which applicants regard as the invention. The claims are further considered to be enabled by the specification so that any person skilled in the art to which the invention pertains, or with which it is most nearly connected, can make and use the same and the best mode contemplated by the inventors of carrying out their invention is clearly set forth. Likewise, all dependent claims, depending from any of the above independent claims are now also in condition for allowance.

Examiner's attention is drawn to one minor amendment, which was made above in allowed claim 67, correcting "an" to "and," to correct a typographical error.

Regarding the art enclosed with the official Action, it is submitted that at least some of the references are irrelevant, as being selected from non-pertinent art areas, such as toe pads, which clearly are no where near the size, nor related in use to the presently claimed invention.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, she is invited to telephone the undersigned at the number provided below.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,

January 30, 2004

By: Rebecca J. Brandau, 33,654
Husch & Eppenberger, LLC
190 Carondelet Plaza, Suite 600
St. Louis, MO 63105
314-480-1872
314-480-1505 FAX